DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment of 01 April 2008 has been entered in full. Claims 1-31 and 34 are canceled. Claim 39 remains withdrawn from consideration as being directed to a non-elected invention. Claims 32, 33, and 35-38 are under examination.

The new sequence listing has been entered.

Withdrawn Objections And/Or Rejections

The application is now fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825.

The rejection of claims 32 and 34 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 3-4 of the previous Office Action (mailed 01 November 2007) is *withdrawn* in view of the canceled and amended claims (received 01 April 2008).

The rejection of claims 32-38 under 35 U.S.C. § 112, first paragraph, regarding new matter, as set forth at p. 8 of the previous Office Action (mailed 01 November 2007) is *withdrawn* in view of the canceled and amended claims (received 01 April 2008).

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A) Scope of Enablement:

Claims 32, 33, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of administering mammalian IP-10 protein for therapeutically treating (1) a female subject to promote conceptus implantation or (2) any subject to chemoattract monocytes or lymphocytes, does not reasonably provide enablement for the methods as broadly claimed, including administration of IP-10 variants, and treatment of other conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis of this rejection is set forth at pp. 4-8 of the previous Office Action (mailed 01 November 2007). It is noted that the claim amendments (received 01 April 2008) have obviated the issue regarding prophylaxis.

B) Inadequate Written Description:

Claims 32, 33, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is set forth at pp. 8-11 of the previous Office Action (mailed 01 November 2007).

Applicant's arguments (pp. 9-11 of remarks received 01 April 2008) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that claim 32 has been amended to reduce scope in order to expedite allowance. Applicant urges that undue experimentation is not required to make and se the full scope of the claimed invention. This has been fully considered but is not found to be persuasive, because claim 32 still encompasses non-mammalian or artificially generated IP-10 proteins. Also, claim 32 specifically recites IP-10 proteins from species for which the structures have not been disclosed.

At p. 10 of the remarks, Applicant argues the enablement requirement only requires that the specification teach the skilled artisan how to make and use the claimed invention. Applicant urges that even if the claimed method does not treat all of the recited conditions all of the time, such is not required for enablement. Applicant argues that the functions of IP-10 and variants are taught in the specification and art, and that such would guide the skilled artisan how to practice the claimed method for all of the noted used. This has been considered but is not found to be persuasive. The functions of IP-10 taught in the specification and prior art are not commensurate in scope with the uses recited in the claims. For example, treating fertility/sterility reads on treatment of both males and females for an incredibly large number of reasons, most of which are completely unrelated to conceptus implantation, such as low sperm count in males and endometriosis in females

Applicant argues that increasing the rate of implantation would treat fertility/sterility issues, interactions between conceptus and maternal systems and pregnancy. Applicant further notes that the activity of IP-10 in stimulating trophoblast migration (associated with placenta), increasing CXCR3 receptor expression in

trophoblasts, elevating trophoblast adhesion to endometrium, elevating integrin expression in trophoblasts, affecting NK cell migration and IL-10 expression are all essential to pregnancy. This has been fully considered but is not found to be persuasive. Again, all of these activities are related to conceptus implantation, and do not support the extremely large genus of conditions associated with fertility and sterility. The evidence is simply not commensurate with the scope of the claims.

Applicant concludes that the person skilled in the art would understand that the claimed method is enabled for all of the goals recited in the claims. This has been fully considered but is not found to be persuasive. For reasons of record, the evidence in the specification and art of record supports the use of mammalian IP-10 protein to promote conceptus implantation in females and chemoattract monocytes or lymphocytes in any subject, but is not commensurate in scope with the claims, which reads on a very large and diverse patient population. Furthermore, evidence in the specification and art of record do not support enablement or written description of the broad genus of IP-10 variant proteins recited in the claims, including IP-10 proteins from specific species listed in claim 33 that have never been disclosed.

Based on the preponderance of the evidence, the rejections are maintained.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6013252 (Terao et al.) in view of Luster et al. for reasons set forth at pp. 11-12 of the previous Office Action (mailed 01 November 2007).

Applicant argues (pp. 11-14, remarks of 01 April 2008) that '252 is directed to promoting conception by administering MCAF or IL-8. Applicant takes issue with '252's assertion that IP-10 is analogous to IL-8. Applicant provides a detailed discussion of the differences between IL-8 and IP-10, both structurally and functionally. Applicant concludes that the prior art fails to disclose or suggest the aspects of the present invention summarized in the arguments. This has been fully considered but is not found to be persuasive. It is clear that the instant specification has disclosed previously unknown activities of IP-10. However, these activities are not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). All that the claims require is administration of an IP-10-like protein to a subject in need of treatment of any one of several diverse fertility-related conditions, including promoting conceptus implantation on the uterine cell wall. '252 clearly suggests using IP-10 to accomplish such at col. 5-6. '252 suggests use of any CXC chemokine, including IP-10. The only information missing from '252 is the structure of IP-10 which was well known in the art, as evidenced by Luster et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to administer an IP-10 protein such as the one fully described by Luster et al.

to promote conceptus implantation as expressly suggested by '252 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number

is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646